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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,371	09/30/2003	Don A. Tanaka	END5098-0515140	5198
26874	7590	08/22/2006	EXAMINER	
FROST BROWN TODD, LLC 2200 PNC CENTER 201 E. FIFTH STREET CINCINNATI, OH 45202			POUS, NATALIE R	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/674,371		TANAKA ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Natalie Pous		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 2,4-9,11-14,16,18,21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,10,15,17,19,20 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/6/05</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of species 2, subspecies 2 (claims 1, 3, 10, 15, 17, 19, 20 and 23) in the reply filed on 7/5/06 is acknowledged. The traversal is on the ground(s) that examination of species 2 would necessarily result in examination of all three species. This is not found persuasive because each requires different structural features that would not necessarily be found in the same search for one structural feature. Further applicant asserts that the feature of subspecies 1 would be inherently included in the search. Examiner respectfully disagrees, as subspecies 1 requires a certain feature that would require further searching beyond the required search subspecies 2.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 10, are rejected under 35 U.S.C. 102(e) as being anticipated by Park et al. (US 2003/0120292).

Regarding Claim 10, Park teaches an anastomotic device, comprising a woven tube of at least one wire strand (18), the woven tube having each longitudinal end terminate in circumferential petals (20), the woven tube having an unactuated position of a generally cylindrical shape (fig. 2) and an actuated position of a hollow rivet shape (fig. 3a) respectively for insertion through and for forming an anastomotic attachment between two proximate tissue walls at an anastomotic surgical site, an underlying portion of each petal presenting a diverging surface to an overlying portion of an adjacent petal (fig. 3b). It is noted that paragraph 38 states "The opposed petals 20 on opposite sides of the two layers of intestine 28, 32 are preferably interdigitated as shown in FIGS. 1, 3A and 3B." as such the configuration of fig. 3b depicts petals on opposing ends of the device (not adjacent petals) sloping toward each other. As such the adjacent petals an underlying portion of each petal presenting a diverging surface to an overlying portion of an adjacent petal.

Regarding Claim 23, Park teaches the anastomosis device of claim 10, wherein the underlying portion of each circumferential petal comprises a monotonic slope shaped to diverge from the overlying portion of the adjacent petal that comprises a monotonic slope. It is noted that the term "diverging" means extending in different directions. As such, the petals, although the monotonic slopes of two adjacent petals are both sloping toward the opposing petals as seen in figure 3B, since the sloping ends of the petals are in different planes, they are diverging.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 15, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (US 2003/0120292) in view of Neuss et al. (US 6355052).

Park teaches all limitations of preceding dependent claim 10 as previously described, and further teaches an anastomotic device, comprising the following:

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- a woven tube (fig. 2) of at least one wire strand (18), the woven tube having each longitudinal end terminate in circumferential petals (20), the woven tube having an unactuated position of a generally cylindrical shape (fig. 2) and an actuated position of a hollow rivet shape (fig. 3a) respectively for insertion through and for forming an anastomotic attachment between two proximate tissue walls at an anastomotic surgical site
- wherein an underlying portion of each petal presenting a diverging surface to an overlying portion of an adjacent petal (fig. 3b). It is noted that paragraph 38 states "The opposed petals 20 on opposite sides of the two layers of intestine 28, 32 are preferably interdigitated as shown in FIGS. 1, 3A and 3B." as such the configuration of fig. 3b depicts petals on opposing ends of the device (not adjacent petals) sloping toward each other. As such the adjacent petals an underlying portion of each petal presenting a diverging surface to an overlying portion of an adjacent petal.
- wherein the underlying portion of each circumferential petal comprises a monotonic slope shaped to diverge from the overlying portion of the adjacent petal that comprises a monotonic slope. It is noted that the term "diverging" means extending in different directions. As such, the petals, although the monotonic slopes of two adjacent petals are both sloping toward the opposing petals as seen in figure 3B, since the sloping ends of the petals are in different planes, they are diverging.

Pulney fails to disclose the structure of the ends of the wires used to form the tube. Neuss teaches a device for insertion into the body (fig. 11a) wherein each wire strand includes unattached ends terminating in a loop (14) in order to reduce the risk of injury. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Park with unattached end portions in the shape of loops in order to reduce the risk of injury.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP  
8/15/06

  
ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER  
